REMARKS/ARGUMENTS

Claims 78, 79, 102-105, 107, 108, and 111 have been examined. As an initial matter, Applicants note that claims 78, 79, and 102-111 were pending in this case prior to issuance of the present office action. Applicants request the examination and status of remaining claims 106, 109, and 110. Further, Applicants request that any further action issued in this case be made non-final so that Applicants may appropriately address these claims.

Claims 78, 106, 110, and 111 have been amended to correct inadvertent typographical errors. New dependent claims 112-115 have been added. Re-examination and reconsideration of pending claims 78, 79, and 102-115 are respectfully requested.

Applicants further note that information disclosure statements were filed with the U.S. Patent Office on October 22, 2002 and April 8, 2004, respectively. Please send confirmation of the consideration of references in these statements prior to the next action.

Rejection under 35 U.S.C. § 102

Claims 78, 79, 102-105, 107, 108, and 111 continue to be rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,299,604 issued to Ragheb et al. This rejection is traversed for the following reasons.

Independent claim 78 recites a method for luminal substance delivery. The method comprises providing a luminal prosthesis comprising a rate limiting barrier which incorporates or couples a substance. In particular, the prosthesis is implanted in a body lumen so that the substance is released from the prosthesis at multiple rates including an initial rate and at least one subsequent rate which is substantially higher than the initial rate and begins after an appreciable preselected time period. This positive recitation has not been reasonably shown or suggested by the cited art.

As the Examiner certainly knows and appreciates, a single cited art reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. §102. M.P.E.P. §2131; *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). The Court of

Appeals for the Federal Circuit has held that, "the identical invention must be shown in as complete detail as is contained in the .... claim." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

In contrast to the present invention, Ragheb et al. does not disclose or suggest the release of a substance at multiple rates, much less an initial rate and at least one subsequent rate which is substantially higher than the initial rate. Applicants have reviewed the Ragheb et al. disclosure in detail including the Examiner citations noted in the present Office Action, but still fail to find any reference or suggestion regarding multiples rates of release of the substance as currently claimed by claim 78. Ragheb et al. is generally directed to a coated implantable medical device (10) comprising a bioactive layer (18) and a porous limiting barrier (20). The disclosures in Ragheb et al. regarding the rate of release for the substance are limited to a single constant rate of release or a total quantity released. See column 13 lines 1-5; column 14 lines 61-64; column 22, lines 39-44. The only mention of a non-constant rate of release is a vague reference to a single geometric rate of release when the substance is contained in a triangular aperture within the stent structure, as shown in FIG. 10D. See column 22 lines 39-44. Assuming *arguendo* that Ragheb et al. provides any teaching at all, such reference given the shape of the aperture (the exposed surface area of the aperture decreasing in size as you move away from the outer surface of the stent) would lead to a decaying rate of release. This falls far short of the present limitation of claim 78 which requires release at "multiple rates including an initial rate and at least one subsequent rate which is substantially higher than the initial rate."

The multiple rate pattern of claim 78 advantageously improves the efficacy of drug delivery by releasing a lower or minimal amount of the substance at an initial rate until a subsequent phase is reached, at which point the release of the substance is substantially higher at a subsequent rate, as shown in Fig. 3 of present application. In particular, the increasing rate of substance release from an initial rate to a subsequent rate is programmed to impact restenosis substantially at the onset of events leading to smooth muscle cell proliferation (hyperplasia). The present invention can further minimize substance washout by timing the subsequent rate of release to occur after an appreciable preselected time period, e.g., after at least initial cellularization and/or endothelialization which creates a barrier over the prosthesis to reduce loss

of the substance directly into the bloodstream. Moreover, the multiple rate pattern of an initial rate and a higher subsequent rate may reduce substance loading and/or substance concentration as well as potentially providing minimal to no hindrance to endothelialization of the vessel wall due to the minimization of drug washout and the increased efficiency of substance release. Prior to the new teachings included for the first time in the present application, no cited art record of reference (including Rabheb et al.) has been shown to remotely teach or suggest this significant release pattern at "multiple rates including an initial rate and at least one subsequent rate which is substantially higher than the initial rate" as recited in claim 78.

Applicants request, if the present rejection is maintained, that the Examiner show or explain where the Ragheb et al. reference teaches or suggest multiple rates as presently claimed in claim 78. "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Found. v. Genentech Inc.*, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991). Absent such a showing, Applicants respectfully request withdrawal of the 35 U.S.C. § 102 rejection and allowance of independent claim 78 (and dependent claims 79 and 102-115).

Added Claims

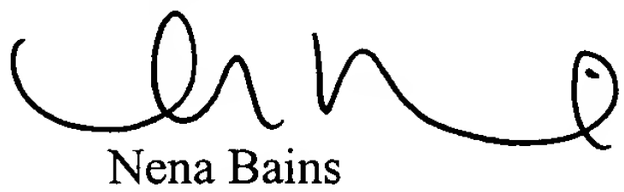
New dependent claims 112-115 have been added. Support for these new claims can be found throughout the originally filed specification. Claims 112-115 depend upon allowable claim 78. As such, Applicants respectfully request allowance of new claims 112-115.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Nena Bains
Reg. No. 47,400

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: 415-576-0300

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